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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,401	CHEN, HONG	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *11 and 13-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/16/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of 09/874,132, issued as US Patent 6,623,947, which is a CIP of 09/586,511, issued as US Patent 6,627,425.

Claims 1-39 are pending. Claims 28-11 and 13-39 are withdrawn. Claims 1-7 and 12 are under consideration.

Election/Restrictions

Applicant's election of Group I (claims 1-7 and 12) in the reply filed on February 6, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-11 and 13-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement filed September 16, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because references C1-C8 do not include the author, title of the article, title of the item, date, pages, etc. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the

submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Specification

Examiner notes that applicants have not updated the relationship of the instant application to its parent application (09/586,511) that has matured into a US patent (US Patent 6,627,425). Examiner urges applicants to amend said information by providing the US patent number in response to this Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

Claims 5-7 and claim 12 depending therefrom are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter.

Claims 5-7, as written, are directed to non-statutory subject matter. Claims 5-7 could read on a host cell still attached to a host such as a human being. The claims do not make it clear that the cell, even though it is a recombinant cell, is an isolated cell. Claims that read on a human being are considered non-statutory. Furthermore, the claims as written do not make it clear that the cell was indeed transformed with the claimed polynucleotides as it recites "contains" or "containing". The claims as written can be interpreted as a cell naturally comprising the claimed polynucleotide but made recombinant due to transformation with any other DNA. Examiner suggests amending the claims to recite "an isolated host cell transformed with..." to overcome the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-2 and 12 and claims 3-7 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 and 12 contain the trademark/trade name "ATCC". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is

used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the clone deposited with ATCC having the accession number PTA-2282 and, accordingly, the identification/description is indefinite. Examiner suggest just the use of accession no.

Claims 1 and 12 and claims 3-7 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite the phrase "a complement". The metes and bounds of the phrase in the context of the above claims are not clear to the Examiner. A polynucleotide that is "a complement" to a given sequence can comprise as little as two nucleic acids. It is not clear to the Examiner, how such sequences can encode a polypeptide having enzymatic activity. Examiner suggests amending the above phrase as "the complement".

Claims 1 and claims 2-7 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "nucleotide residues". The metes and bounds of the phrase in the context of the above claims are not clear to the Examiner. The term

"residue" is used to describe amino acid units of a polypeptide and not a polynucleotide. Examiner suggests amending the above phrase as "nucleotides".

Claims 1 and 12 and claims 3-7 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recite the phrase "hybridizes ...under stringent conditions". The metes and bounds of the phrase in the context of the above claims are not clear to the Examiner. It is not clear to the Examiner as to what hybridization conditions are encompassed in the phrase (i.e. low stringency, high stringency, etc.). A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. Therefore, it is unclear from the specification or from the claims as to what applicants mean by the above phrase. Examiner requests clarification.

Claims 5 and 7 and claim 6 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 7 recite the phrase "host cell which contains" and "host cell containing". The metes and bounds of the phrase in the context of the above claims are not clear to the Examiner. It is not clear to the Examiner as to what applicants mean by host cells "containing" or "which contains" polynucleotides. A perusal of the specification did not provide the Examiner with a specific definition for the above

phrase. Examiner suggests amending the claims as "host cell transformed with", for example.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7 and 12 are directed to polynucleotides selected from group consisting of: A) polynucleotides having at least 91% sequence identity to SEQ ID NO:1 or 2, B) polynucleotides comprising at least 35 nucleotides of SEQ ID NO:1 or 2 or a complement thereof, C) polynucleotides encoding a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3, D) polynucleotides encoding allelic variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under stringent conditions and E) polynucleotides of A)-D) further comprising polynucleotides encoding a heterologous polypeptide, wherein said polynucleotides of A)-D) encode polypeptides having any or no function, and vectors and host cells comprising said polynucleotide and a method of producing

polypeptides encoded by the polynucleotides of A), C) and D). The claims encompass A) polynucleotides having at least 91% sequence identity to SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, and having any or no function, B) any or all polynucleotides comprising any 35 nucleotides of SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, and having no or any function, C) polynucleotide encoding any or all fragments comprising any 15 consecutive amino acids of SEQ ID NO:3, including any or all recombinants, mutants and variants thereof, and having any or no function, D) polynucleotides encoding any or all allelic variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under any stringent conditions and having any or no function and E) polynucleotides of A)-D) further comprising any or all polynucleotides encoding any or all heterologous polypeptide, including any or all recombinants, mutants and variants thereof, and having any or no function. Therefore, the claims are drawn to a genus of polynucleotide encoding polypeptides having any structure and any or no function. There is no disclosure of any particular structure to function/activity relationship in the disclosed species.

The specification only describes a polynucleotide of SEQ ID NO:1 or 2 encoding a polypeptide of SEQ ID NO:3 having glucose-6-phosphatase activity. This one example is not enough and does not constitute a representative number of species to describe the whole genus of any or all variants, recombinant and mutants of SEQ ID NO:1 or 2 or polynucleotides encoding any or all variants, recombinants and mutants of SEQ ID NO:3 and there is no evidence on the record of the relationship between the

structure of the polypeptide of SEQ ID NO:3 and the structure of any or all recombinant, variant and mutant polypeptides. Therefore, the specification fails to describe a representative species of the genus comprising any or all variants, recombinants and mutants of SEQ ID NO:1 or 2 and polynucleotides encoding any or all variants, recombinants and mutants of SEQ ID NO:3.

The claims are also drawn to polynucleotides encoding many functionally unrelated polypeptides encompassed within the scope of these clams, including partial sequences. The genus of these polynucleotides comprise a large variable genus with the potentiality of encompassing many different polynucleotides encoding polypeptides having different structure and activity or no activity. The specification only describes polypeptide of SEQ ID NO:3 having glucose-6-phosphatase activity encoded by the polynucleotide of SEQ ID NO:1 and 2. The specification fails to describe additional representative species of the polypeptides by any identifying characteristics or properties of the polypeptides, for which no predictability of function is apparent. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The claims (claim 1 e) and claim 12 c)) are also drawn to polynucleotides encoding all possible allelic variants of SEQ ID NO:3, wherein said polynucleotides hybridize to SEQ ID NO:1 or 2 under hybridization conditions. The claims encompass polynucleotides encoding any variants and mutants including allelic variants of SEQ ID NO:3. Therefore, the claims are drawn to a genus of polynucleotides encoding polypeptides having any function or no function at all. "Allelic sequences" are an

alternative form of the gene which may result in at least one mutation in the nucleic acid sequence. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. However, this definition does not provide any specific information about the function of polynucleotides encoding naturally occurring (alleles) variants of SEQ ID NO:3 (i.e. where in the regions within which mutations are likely to occur). There is no description of the function of how the structure of SEQ ID NO:3 relates to the function of any naturally occurring alleles. The general knowledge in the art concerning alleles does not provide any indication of how one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art, structure or function of one does not provide guidance to the structure and function of others.

Given this lack of additional representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-7 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO:1 or 2 encoding a polypeptide of SEQ ID NO:3 and glucose-6-phosphatase activity, does not

reasonably provide enablement for A) polynucleotides having at least 91% sequence identity to SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, B) any or all polynucleotides comprising any 35 nucleotides of SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, C) polynucleotide encoding any or all fragments comprising any 15 consecutive amino acids of SEQ ID NO:3, including any or all recombinants, mutants and variants thereof, D) polynucleotides encoding any or variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under any stringent conditions, including any or all recombinants, mutants and variants thereof and E) polynucleotides of A)-D) further comprising any or all polynucleotides encoding any or all heterologous polypeptide, including any or all recombinants, mutants and variants thereof and wherein the polynucleotides of A)-E) encode polypeptides having any or no function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 1-7 and 12 are directed to polynucleotides selected from group consisting of: A) polynucleotides having at least 91% sequence identity to SEQ ID NO:1 or 2, B) polynucleotides comprising at least 35 nucleotides of SEQ ID NO:1 or 2 or a complement thereof, C) polynucleotides encoding a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3, D) polynucleotides encoding variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under stringent conditions and E) polynucleotides of A)-D) further comprising polynucleotides encoding a heterologous polypeptide, wherein said polynucleotides of A)-D) encode polypeptides having any or no function, and vectors and host cells comprising said polynucleotide and a method of producing polypeptides encoded by the polynucleotides of A), C) and D). The claims encompass A) polynucleotides having at least 91% sequence identity to SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, and having any or no function, B) any or all polynucleotides comprising any 35 nucleotides of SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, and having no or any function, C) polynucleotide encoding any or all fragments comprising any 15 consecutive amino acids of SEQ ID NO:3, including any or all recombinants, mutants and variants thereof, and having any or no function, D) polynucleotides encoding any or all variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under any stringent conditions and having any or no function and E) polynucleotides of A)-D) further comprising any or all polynucleotides encoding any or all heterologous polypeptide, including any or all recombinants, mutants and variants thereof, and having

any or no function. Therefore, the claims are drawn polynucleotides encoding polypeptides having any structure and any function or no function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of any or all variants, mutants and recombinants of SEQ ID NO:1 or 2 and polynucleotides encoding any or all variants and mutants of SEQ ID NO:3, broadly encompassed by the claims. Since the amino acid sequence of the encoded protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to a polynucleotide of SEQ ID NO:1 or 2 encoding a polypeptide of SEQ ID NO:3 having glucose-6-phosphatase activity. It would require undue experimentation of the skilled artisan to make and use the claimed variants, mutants and recombinants of SEQ ID NO:1 or 2 encoding variants, mutants and recombinants of SEQ ID NO:3. In view of the great breadth of the claim, amount of experimentation required to make the claimed polynucleotides, the lack of guidance, working examples, and unpredictability of the art in predicting function from the encoded polypeptide's primary structure, the claimed invention would require undue

experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polynucleotides encompassed by these claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass A) polynucleotides having at least 91% sequence identity to SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, B) any or all polynucleotides comprising any 35 nucleotides of SEQ ID NO:1 or 2, including any or all recombinants, mutants and variants thereof, C) polynucleotide encoding any or all fragments comprising any 15 consecutive amino acids of SEQ ID NO:3, including any or all recombinants, mutants and variants thereof, D) polynucleotides encoding any or variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under any stringent conditions, including any or all recombinants, mutants and variants thereof and E) polynucleotides of A)-D) further comprising any or all polynucleotides encoding any or all heterologous polypeptide, including any or all recombinants, mutants and variants thereof because the specification does not establish: (1) regions of

the protein structure which may be modified without affecting glucose-6phosphatase activity; (2) the general tolerance of glucose-6phosphatase to modification and extent of such tolerance; (3) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (4) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The claims also broadly encompass polynucleotides encoding variants, mutants and recombinants having glucose-6phosphatase activity, but polypeptides having any function or having no function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides having any function or having no activity. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and identifying a use for the polypeptide would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is known

regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the encoded polypeptides.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any or all variants, mutants, recombinants and fragments of the polynucleotide of SEQ ID NO:1 or 2 and polynucleotides encoding any or all variants, mutants and recombinants of SEQ ID NO:3, wherein the encoded polypeptides have glucose-6-phosphatase activity, any activity or no activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any or all mutants, variants, recombinants and fragments of SEQ ID NO:1 or 2 having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1-7 and 12 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel clone. Since the clone is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the

specification or otherwise be readily available to the public. The claimed sequence of the clone is not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the microorganism should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that applicants have deposited the clone in a depository. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that: 1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request; 2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808; 3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of

the patent, whichever is longer; and 4. the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Arden et al.

Claims 1, 3, 5-7 and 12 are drawn to a polynucleotide encoding a polypeptide comprising a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3, vector and non-human mammalian host cell comprising said polynucleotide and a method of producing said polypeptide.

Arden et al. (Diabetes. 1999 Mar;48(3):531-42 - form PTO-892) discloses a polynucleotide encoding a polypeptide having at least 85% sequence identity to SEQ ID NO:3 of the instant invention (See "Sequence Alignment SEQ ID NO:3" – form PTO-892 and page 534 of Arden et al.). The polynucleotide of Arden et al. encodes a polypeptide comprising a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3 (See "Sequence Alignment SEQ ID NO:3" – form PTO-892 and page 534 of Arden et al.). The reference of Arden et al. also discloses a vector and non-human mammalian host cell comprising said polynucleotide

and a method of producing said polypeptide. Therefore, the reference of Arden et al. anticipates claims 1, 3, 5-7 and 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arden et al. in view of Smith et al.

Claim 4 is drawn to a polynucleotide encoding a polypeptide comprising a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3, and further comprising a polynucleotide encoding a heterologous polypeptide.

Arden et al. discloses a polynucleotide encoding a polypeptide comprising a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3.

The difference between the reference of Arden et al. and the instant invention is that the reference of Arden et al. does not teach a polynucleotide encoding a polypeptide comprising of a fragment of SEQ ID NO:3 and further comprising a polynucleotide encoding a heterologous polypeptide.

However, fusing heterologous polypeptides to a protein of interest is very well known and practiced in the art. For example, Smith et al. (U.S. Patent No. 5,654,176 – form PTO-892) discloses a polynucleotide encoding a foreign protein of interest fused to a glutathione-S-transferase (GST) (abstract and Columns 2-3). Smith et al. teaches that said polynucleotide is useful in facilitating the purification of the protein of interest (Column 2).

Therefore, in combining the references of Arden et al. and Smith et al, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a polynucleotide encoding a fusion protein comprising the polypeptide of Arden et al. and a GST, as taught by Smith et al. One of ordinary skill in the art would have been motivated to make a polynucleotide encoding said fusion protein in order to facilitate purification of the polypeptide of Arden et al. One of ordinary skill in the art would have had a reasonable expectation of success in making a polynucleotide encoding said fusion protein because Smith et al. successfully teaches how to make such a polynucleotide.

Therefore, Arden et al. and Smith et al. render claim 4 *prima facie* obvious to those skilled in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of US Patent No. 6,627,425. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: Claims 1-7 and 12 of the instant application and claims 1-24 are both directed to A) a polynucleotide having at least 91% sequence identity to SEQ ID NO:1 or 2, B) polynucleotide encoding the polypeptide of SEQ ID NO:3 and C) polynucleotides of A)-B further comprising polynucleotides encoding a heterologous polypeptide and vectors and host cells comprising said polynucleotide and a method of producing polypeptides encoded by said polynucleotides. The polynucleotide of SEQ ID NOs:1 and 2 and its encoded polypeptide of SEQ ID NO: 3 of the instant application are 100% identical to the polynucleotide of SEQ ID NOs:1 and 2 and its encoded polypeptide of SEQ ID NO:3 of U. S. Patent No. 6,627,425.

Claims 1-7 and 12 of the instant application are drawn to A) polynucleotides comprising a fragment comprising 35 nucleotides of SEQ ID NO:1 or 2 or a complement thereof, B) polynucleotides encoding a fragment of SEQ ID NO:3, wherein the fragment comprises at least 15 consecutive amino acids of SEQ ID NO:3 and C) polynucleotides

encoding allelic variants of SEQ ID NO:3 wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under stringent conditions. Claims 1-24 of U. S. Patent No. 6,627,425 are drawn to A) polynucleotides comprising a fragment comprising 165 nucleotides of SEQ ID NO:1 or 2 or a complement thereof, B) polynucleotides encoding a fragment of SEQ ID NO:3, wherein the fragment comprises at least 30 consecutive amino acids of SEQ ID NO:3 and C) polynucleotides hybridizing with SEQ ID NO:1 or 2 under stringent conditions. A polynucleotide comprising 35 nucleotides of SEQ ID NO:1 or 2, a polynucleotide encoding a fragment comprising 15 amino acids of SEQ ID NO:2 and a polynucleotide encoding an allelic variant of SEQ ID NO: wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under stringent conditions are specific embodiments of the polynucleotides described in the reference patent. The specification of the reference patent supports a polynucleotide comprising 35 nucleotides of SEQ ID NO:1 or 2, a polynucleotide encoding a fragment comprising 15 amino acids of SEQ ID NO:2 and a polynucleotide encoding an allelic variant of SEQ ID NO: wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under stringent conditions (Columns 4-30) and polynucleotides comprising SEQ ID NOs: 1 or 2 that would anticipate the polynucleotide of claims 1-4, vectors and host cells of claims 5-7 and the method of claim 12. Claims 1-7 and 12 of the instant application cannot be considered patentably distinct over claims 1-24 of the reference application when there is specifically recited embodiment that would anticipate claims 1-7 and 12 of the instant application. Alternatively, claims 1-7 and 12 of the instant application cannot be considered patentably distinct over claims 1-24 of the reference patent because it would

have been obvious to one having ordinary skill in the art to modify claims 1-24 of the reference patent by selecting a specifically disclosed embodiment that supports those claimed, i.e. a polynucleotide comprising 35 nucleotides of SEQ ID NO:1 or 2, a polynucleotide encoding a fragment comprising 15 amino acids of SEQ ID NO:2 and a polynucleotide encoding an allelic variant of SEQ ID NO: wherein the polynucleotide hybridizes with SEQ ID NO:1 or 2 under stringent. One of ordinary skill in the art would have been motivated to do this because the embodiments claimed in the instant claims are disclosed as being a preferred embodiment within claims 1-24 of the reference patent. Therefore, the conflicting claims are not patentably distinct from each other.

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652

Manjunath Rao
Primary Patent Examiner 1652